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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,493

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EXAMINER

MUI, CHRISTINE T

ART UNIT

PAPER NUMBER

1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,493	<b>Applicant(s)</b> SCHNETZ ET AL.	
	<b>Examiner</b> CHRISTINE T. MUI	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 40-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06 October 2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of claims 40-68 in the reply filed on 21 December 2007 is acknowledged.

### ***Drawings***

2. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

### ***Claim Objections***

3. Claim 55 is objected to because of the following informalities:
4. In line 2 of the instant claim where it reads 'markings..' should be changed to 'markings.' . Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 40-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,103,518 to Leighton (submitted on the Information Disclosure Statement on 06 October 2006).

9. Regarding claims 40-42, the reference Leighton discloses an instrument for constructing tissue arrays. A simple, robust and precise instrument for constructing tissue arrays includes multiple punches mounted on a punch platform. Mechanical détentes or stops are provided which mechanically arrest the movement of the punch platform in the precisely defined positions. The step of moving the punch platform from

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a first position to a second position, either punch can be quickly brought into operating position (and the other moved into a non-interfering position) by either manually or by automatic means. The arrays are constructed by taking samples from a series of donor tissues, one at a time, using a hollow, preferably needlelike, donor punch and placing each sample sequentially in the recipient of complementary shape in a recipient material by a recipient punch, thereby forming an array of tissues in the recipient block. Each punch comprises a punch tube and an associated stylet guided within the punch tube. In the process for forming a hole in a recipient material such as paraffin, taking a sample of tissue from a donor specimen, and planting the sample in the hole in the recipient material, is repeated until a tissue array is formed comprising of hundreds of tissue samples arranged in assigned location in the recipient material. The donor block can be mounted on a slide that is inspected under a microscope and target sites can be plotted and recorded in a computer. The slide from the donor block may also be stained to reveal structures of interest and be superposed over the donor bloc and the donor punch be aligned over the target site. The slide is then optionally removed and the donor punch is brought down to punch the donor block in the selected position. Prior to punching in the donor block, bore holes are punched from a recipient block that may be alternatively removed and replaced in the holder during the process and the punched samples from the donor tissue sample fits snugly in the recipient block and a precise array is created (see abstract, column 5, lines 1-10, column 7, lines 4-58). It is interpreted by the examiner that the stained target sites are the markings on the superposed slides. Leighton does not specifically disclose superimposing a digital

image on a surface, but it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a digital, microscopic image rather than just an image of a target site that can be view under a microscope so that one can observe the markings of target sites of interest in a zoomed in view where the image is easily observed in an expanded version.

10. Regarding claims 43-44, the reference Leighton discloses a section of the donor block (which is assumed to be representative of the tissue imbedded in the entire donor block) can be mounted on a slide, inspected under a microscope. The target sites can be selected and the donor block is punched at the selected site the manual adjustment of the micrometer drives or by feeding the coordinates to a CNC controlled X-, Y-positioning means (see column 7, lines 42-52). Leighton does not specifically disclose the images that are superimposed are of several segments or they are straightened or had artifacts eliminated prior to superimposing the image, but it would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange the sample that is superimposed from the slide to reveal structures of target sites are of several segments or have been straightened or parts eliminated so that upon punching selected areas are punched and placed in a recipient to create a unique array.

11. Regarding claims 45-46, the reference Leighton discloses a section of the donor block (which is assumed to be representative of the tissue imbedded in the entire donor block) can be mounted on a slide, inspected under a microscope and target sites can be plotted and recorded in a computer (see column7, lines 42-47).

12. Regarding claim 47, the reference Leighton discloses the target sites on the donor block can be plotted and recorded in a computer (see column 7, lines 42-48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to change the display scale and setting of the computer can be modified to properly display the array either to zoom in to observe the array in at a magnified level or zoomed out so that one can observe the entire array from afar.

13. Regarding claims 48-49, the reference Leighton discloses a section of the donor block (which is assumed to be representative of the tissue imbedded in the entire donor block) can be mounted on a slide, inspected under a microscope and target sites can be plotted and recorded in a computer. The slide can be superposed over the donor block and aligned over target sites (see column 7, lines 42-47). It is interpreted by the examiner that the when the slide is aligned over target sites of the donor block, it is considered that the position of the slide may be modified to obtain proper alignment or orientation over the donor block to obtain specific samples for the construction of the array.

14. Regarding claims 50-52, the reference Leighton discloses the slide made from the donor block that represents a section of the donor block, can be stained to reveal the structures of interest (see column 7, lines 51-57). It is interpreted by the examiner that the staining of the slide may be modified in its color, translucency or transparency to reveal different structures of interest that will be examined.

15. Regarding claim 53, the reference Leighton discloses a section of the donor block (which is assumed to be representative of the tissue imbedded in the entire donor

block) can be mounted on a slide, inspected under a microscope and target sites can be plotted and recorded in a computer. The slide from the donor block could be stained to reveal structures of interest if necessary and be superposed over the donor block and the donor punches be aligned over the target site. Once the available target site is selected and the donor block is punched at the selected site either by manual adjustment or the micrometer drives or by feeding the coordinates to a CNC controlled X-, Y- positioning means (see column 7, lines 42-57). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide patient information along with the superimposed image from the microscope and computer to store and reveal all information available of the stained target site slide to readily provide information about the target of interest.

16. Regarding claims 54-55, the reference Leighton discloses a section of the donor block (which is assumed to be representative of the tissue imbedded in the entire donor block) can be mounted on a slide, inspected under a microscope and target sites can be plotted and recorded in a computer. The slide from the donor block could be stained to reveal structures of interest if necessary and be superposed over the donor block and the donor punches be aligned over the target site. Once the available target site is selected and the donor block is punched at the selected site either by manual adjustment o the micrometer drives or by feeding the coordinates to a CNC controlled X-, Y- positioning means (see column7, lines 42-57). It is interpreted by the examiner that where the slides those are stained revealing target site is considered to be



characterized and the CNC controlled X-, Y- positioning means is capable of number or recording the target sites of interest.

17. Regarding claims 56-57, the reference Leighton discloses the slide made from the donor block could be stained to reveal structures of interest if necessary and be superposed over the donor block and the donor punch be aligned over the target site. The slide can then be removed and the donor punch may be brought down to punch the donor block in the selected position (see column 7, lines 52-58). It is interpreted by the examiner that the slide that can be removed with stained target sites from the donor block are selected for punching and then removed for punching may be modified with a different stain to reveal different target sites or erase targets by adding a solvent or solution to reverse staining of target sites. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify or erase the marking of interest to be punched in a tissue sample to change the content of the array to be analyzed.

18. Regarding claim 58, the reference Leighton discloses that a section of the donor block can be mounted on a slide, inspected under a microscope and the target sites plotted and recorded in a computer (see column 7, lines 42-48). It is interpreted by the examiner that the target sites that are plotted and recorded in a computer can also have annotations added in information about the site regarding its position of the target site or other important information in the block or the hole. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide at least one annotation to the markings to provide the most information possible about the sample

so that everything about the target site is recorded for examining purposed or for addition information.

19. Regarding claim 59-60, the reference Leighton discloses that when a donor punch is to be expelled from the stylet, a bridge and donor block are removed from the base plate where it positioned above a stationary recipient block and the donor punch is moved vertically downward to just above the hole in the recipient block where the position of the recipient block surface has been measured and recorded as part of the step of recipient block core hole formation. The stylet then expels the core sample from the donor punch tube into the recipient hole in the recipient block. Since the recipient block has not been moved, the precise position of the recipient block is assured (see column 13, lines 1-10). It is interpreted by the examiner that where the stylet obtains cores tissue samples that are optionally stained in specific sections to reveal target sites of interest, deposits the sample in a recipient block positioned below the donor block. It would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange the recipient block and the stained slides on the donor block positioned in such as way so that holes in the recipient block correspond to specific target sites for the construction of the array so that upon analysis one can conduct the analysis based upon known target sites or markings of a sample.

20. Regarding claim 62, the reference Leighton discloses the stylet that is used to punch holes in the block within a punch tube that is used as a probe to sense the surface of the recipient block or the donor block. The stylet is manufactured to protrude a fixed and known distance from the bottom of the punch tube when the punch tube is

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empty of donor or recipient material. Control means are provided to record where the stylet is on the block to record the current position of the punch and the position of the surface of the block. The samples are obtained from a donor punch that is provided on the pivot arm that pivots manually by an operator or automatically about a horizontal axis from one end position to the other (see column 11, lines 12-35, column 12, lines 28-37).

21. Regarding claim 63, the reference Leighton discloses using a stylet to punch holes in the recipient block and the donor block. The stylet has a punch tube as the probe to sense the surface of the block before the bore or hole is punched out the block. The stylet is manufactured to protrude a fixed and known distance from the bottom of the punch tube when the punch tube is empty of donor or recipient material and the stylet extends all the way to the bottom of the bottom of the punch. As the punch is brought down to the block, the stylet will be the first element to touch the block. The stylet tip remains resting on the surface of the block but the punch will continue to move downward relative to the block and relative to the stylet. The control means can then record the signal corresponding to the current position of the punch and record the position of the surface of the block (see column 11, lines 12-35).

22. Regarding claim 64, the reference Leighton discloses that when the stylet contacts the block surface during a downward movement of the punch a flange to flange electrical contact is broken and a signal is sent or interrupted to the controller. The computer or controller registers the surface position at the locus on the array and provides control signal to continue moving the punch downwards for a predetermined

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distance until the punch tube has penetrated the desired distance into the block (see column 11, lines 53-62).

23. Regarding claim 65, the reference Leighton discloses the slide made from the donor block that represents a section of the donor block, can be stained to reveal the structures of interest (see column 7, lines 51-57). The instrument may be fully manually operated, semi-automated or automated and be provided with means such as an electromagnetic actuator means or hydraulic or pneumatic cylinder to pivot the member between a first and second position for punching bores in the blocks. It would have been obvious to one having ordinary skill in the art at the time the invention was made to program the hole punching process in the donor block for obtaining tissue samples after the last stained target site is placed on the donor block with the computer or controllers to ensure that the markings or stained targets are obtained in a timely manner just in case the stain only reveals the targets for a specified amount of time.

24. Regarding claim 66, the reference Leighton discloses a waste tray is placed below the raised recipient punch or the recipient punch is pivoted out to the inactive position at which time the recipient punch tip is positioned over a was tray and the controller sends a signal to cause the stylet to return to the start position with the stylet tip protruding from the end of the recipient punch tube. As the stylet moves back to the starting position, the stylet expels any material from the recipient punch tube (see column 12, lines 11-27). It is interpreted by the examiner that when the stylet is moved back and forth from the waste tray to expel punched material, this is considered to be a part of the punching procedure that is interrupted and continued. Furthermore, when

the stylet is moved back to the starting position, the stylet expels any material from within the recipient punch tube. Contact is made between the style and the punch tube flanges which sends a signal to the control recipient the style has successfully returned to the start position and is ready for use. Failure of the stylet to return to the start position can generate a failure signal and/or alarm and cause automatic interruption of the array construction process (see column 12, lines 11-27). It is interpreted by the examiner that when the stylet is returned to the punch tube flanges, the process for constructing arrays is interrupted when the stylet is not in contact and resumed when the stylet and flanges are in contact.

25. Regarding claim 67, the reference Leighton discloses a recipient block that has recipient punches positioned over the target site of the block. The instrument moved the punch down the desired distance measured from the top of the surface at the locus of interest and the instrument punches out bore holes in the block. The recipient block is then removed and replaced by a donor block where donor punch to remove core tissue sample from the donor block in the same manner as that the recipient punch is removed a core of material from the recipient block. A vertical motion of the punch relative to the donor block (i.e. the lowering of the punch or a raising of the donor block, followed by the reverse motion) is used to obtain a sample core from a region of interest in the donor block (see column 10, lines 26-32, column 12, lines 59-67).

26. Regarding claim 68, the reference Leighton discloses a waste tray is placed below the raised recipient punch or the recipient punch is pivoted out to the inactive position at which time the recipient punch tip is positioned over a waste tray and the

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controller sends a signal to cause the stylet to return to the start position with the stylet tip protruding from the end of the recipient punch tube. As the stylet moves back to the starting position, the stylet expels any material from the recipient punch tube (see column 12, lines 11-27). It is interpreted by the examiner that when the stylet is moved over the waste tray to expel the punch material, it is cleaned after the hole and/or donor punchings. It would have been obvious to one having ordinary skill in the art at the time the invention was made to clear the stylet of the punch material after each use or after at least several sample punching so that when new punches are made clean holes or punches are made.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE T. MUI whose telephone number is (571)270-3243. The examiner can normally be reached on Monday-Thursday 7-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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CTM

/Walter D. Griffin/  
Supervisory Patent Examiner, Art Unit 1797